In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 21-1513V

PORTIA EXUM,	*	Chief Special Master Corcoran
Petitioner,	*	Dated: August 29, 2024
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Amber Diane Wilson, Wilson Science Law, Washington, DC, for Petitioner.

Lauren Kells, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On June 25, 2021, Portia Exum filed a petition seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] Petitioner alleges that the tetanus-diphtheria-acellular pertussis ("Tdap") and measles-mumps-rubella ("MMR") vaccines she received on October 8, 2018, caused her to develop autoimmune hepatitis ("AIH"). Pet. at 1. A one-day Entitlement Hearing was held on March 7, 2024. Now, having heard the witnesses at hearing and reviewed the record, I find Petitioner is not entitled to compensation.

[1] Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Ruling will be available to the public in its present form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

I. Factual Background

Pre-Vaccination History

Ms. Exum was born on January 29, 1988. Prior to the vaccinations at issue, she had a history of gastrointestinal reflux issues, small intestinal bacterial overgrowth, and kidney stones at different times. Ex. 2 at 9–12; Ex. 3 at 273–75, 265–71. Notably, during a May 2018 ER visit for kidney stones, Petitioner's AST and ALT levels (liver enzymes) were normal. Ex. 3 at 268.

Petitioner began preparing for overseas travel to Kenya and Tanzania in mid-August 2018. She received anti-malarial medication on August 17, 2018. Ex. 3 at 74. She was instructed to begin taking the medication two days before visiting areas with high risk for malaria, and to continue taking it for seven more days after leaving. *Id*. On August 20, 2018, she received the MMR and Tdap vaccines from her employer's health clinic, but declined the typhoid vaccine. *Id.* at 72–73.

Post-Vaccination Period and Symptoms Onset

Petitioner traveled to Kenya and Tanzania from August 29 to September 8, 2018. Ex. 4 at 35. She reported receiving four or five bug bites during the trip. *Id.* Upon return, she felt fatigued, and had GERD symptoms and indigestion in late September. *Id.* In October 2018, she reported experiencing daily nausea. *Id.*

On October 26, 2018, Petitioner had a routine physical for life insurance purposes that revealed elevated liver enzymes. Ex. 4 at 42 (ALT of 818 U/L with a 0-45 U/L range, AST of 546 U/L with a 0-33 U/L normal range). She followed up with a gastroenterologist on November 28, 2018, to address both the elevated liver enzymes and her ongoing nausea, as well as related GI symptoms. Ex. 3 at 280. Her abdominal exam was unremarkable, with no signs of liver enlargement or tenderness. *Id.* A physician's assistant ("PA") noted her recent abnormal liver function tests, and that Petitioner reported right-sided distress. *Id.* at 282. The PA recommended *H. pylori* testing, and that Petitioner use Pepcid and diet modifications to ease her GERD and dyspepsia. *Id.* Petitioner was referred to a hepatologist to have an MRI of her liver. *Id.* at 283. Test results two days after this visit showed even higher AST and ALT levels, but samples were negative for H. pylori. *Id.* at 67–69.

Petitioner's next treatment event occurred over five weeks later at a visit to her primary care physician ("PCP") on December 7, 2018. Ex. 3 at 61. She now reported upper right quadrant abdominal pain, nausea, fatigue, and yellow eyes. Id. An abdominal exam was unremarkable, and her PCP referred her to a hepatologist. *Id*. at 63. She also had her inter-uterine device ("IUD") removed on December 6, 2018, to eliminate it as a potential source of the liver issues. *Id.* at 242–243. She then visited the same PCP on December 14, 2018, expressing concern for malaria or other

insect diseases resulting from big bites during recent travel. *Id.* at 57. The PCP ordered additional lab work, and referred her to an infectious disease specialist. *Id*. at 59. The lab work again showed elevated AST and ALT, but autoantibody testing for markers associated with AIH (anti-nuclear antibodies and anti-smooth muscle antibodies) were negative. *Id*. at 58.

On December 19, 2019, Petitioner saw a hepatologist for her elevated liver enzymes. Ex. 3 at 232–38. She denied the presence of known risk factors for liver disease, such as alcohol consumption or IV drug use. *Id*. at 232. She did acknowledge taking antimalarial medication during travel, but denied taking any over-the-counter medications or supplements other than reishi mushrooms. *Id*. The hepatologist noted that she had no signs of decompensated liver disease, including icterus, jaundice, confusion, melena, hematochezia, hematemesis, bruising, weight loss, or abdominal swelling, and an abdominal exam was again unremarkable. *Id*. at 232–33, 235. But her liver MRI showed two hyper-intense lesions consistent with adenomas versus focal nodular hyperplasia ("FNH"), and asymmetric dilation of the left renal vein. *Id*. at 235–36. The diagnostic differential included elevated results from liver function tests ("LFTs"), and hepatic adenoma versus FNH. *Id*. at 237. Lab results again showed elevated LFTs, but no signs of active hepatitis infection. Ex. 8 at 73. The hepatologist ordered a liver biopsy and a repeat liver MRI with contrast in six months. Ex. 3 at 237.

Petitioner underwent the liver biopsy on January 3, 2019, which expanded her differential diagnoses to "infection, the effects of medications/drugs/herbal remedies, Wilson disease and autoimmune hepatitis." Ex. 3 at 229. The next day, she saw a hematology and oncology specialist, who stated that her elevated LFTs were due to "obvious liver disease" that he diagnosed as hepatitis. *Id.* at 222.

Subsequent Treatment for Hepatitis

On January 29, 2019, Petitioner visited an infectious disease specialist. Ex. 4 at 6. They discussed her international travel from the early fall of 2018, and she reported that she had entered bodies of water, received several insect bites, and felt extreme fatigue upon return. *Id*. at 8. The specialist noted she was taking a four to six-week course of prednisone. *Id*. at 6. He affirmed Petitioner's hepatitis diagnosis, and ordered lab work. *Id.* at 8. The results revealed Petitioner had experienced an Epstein-Barr viral infection at some prior point. *Id*. at 12; Ex. 3 at 207. Her LFTs had improved, but were still elevated. Ex. 3 at 204.

Petitioner's LFTs thereafter trended downwards during February and March 2019, but remained elevated. Ex. 3 at 43–51. During a GI visit for reflux management in February, her treater noted that she was taking kidney-oriented medication in addition to the prednisone to treat her liver issues. *Id.* at 197. Her PCP later noted in April 2019 that her AIH was "improving." *Id*. at 36–37. A visit to a hepatologist that same month revealed continued LFT improvement, although

levels remained above normal. *Id.* at 192–96. She also continued to report some ongoing fatigue. *Id.* at 34.

Petitioner visited her hepatologist again in August 2019. Ex. 3 at 162–65. Her LFTs remained elevated, and the hepatologist ordered a metabolic screen to rule out hepatoxicity, and instructed her to continue with her previously-prescribed medications. *Id*. at 165. Labs taken shortly thereafter in September 2019 showed slightly elevated LFTs, but otherwise normal results. *Id.* at 20–31.

By the first half of 2020, Petitioner's liver concerns had mostly resolved, and testing began from this time to 2022 to reveal normal LFTs. Ex. 10 at 56–61; Ex. 3 at 154. A repeat liver biopsy performed in February 2021, however, showed "chronic hepatitis with minimal interface activity and mild portal fibrosis (stage 1 of 4)." Ex. 14 at 41; Ex. 15 at 83. But a hepatology follow-up in March 2022 revealed no signs of liver disease, and the latest records filed in this case show no signs of liver disease through November 2023. Ex. 14 at 36–41; Ex. 46 at 6–7.

II. Hearing Witnesses

A. Petitioner's Expert – Dr. Robert Gish, M.D.

Dr. Gish prepared two reports in this case. Gish First Report, dated July 11, 2022, filed as Ex. 16 (ECF No. 18-1) ("Gish First Rep."); Gish Supplemental Report, dated March 21, 2023, filed as Ex. 38 (ECF No. 28-1). He also testified at the hearing.

Dr. Gish received his M.D. from the University of Kansas, and completed his internship and residency at the University of California, San Diego. Gish CV at 3, filed on July 11, 2022, as Ex. 37 (ECF No. 20-1). He then completed a fellowship in gastroenterology and hepatology, with a special rotation in liver transplantation, at UCLA. *Id*. He is board-certified in internal medicine and gastroenterology, and has a separate board certification for hepatology that is part of the Certificate of Advanced Qualification in liver transplantation. *Id*. at 2. He is a member of multiple professional societies including the National Viral Hepatitis Round Table, the American Association for the Study of Liver Disease, and the American Liver Foundation. *Id*. at 4. He is a licensed physician in California, Arizona (inactive), and Nevada. *Id*. at 2. He has been active as a clinician and researcher for thirty-six years and has served on the editorial boards of many prestigious journals in his field, including *Hepatology* and the *Journal of Viral Hepatitis.* Gish First Report at 1.

Presently, Dr. Gish is a clinical adjunct professor of medicine at the University of Nevada School of Medicine in both Reno and Las Vegas, and UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences. Gish CV at 1. He is also the Medical Director of the Hepatitis B Foundation, which is the nation's leading nonprofit research and advocacy organization for

hepatitis B (HBV). *Id.* Dr. Gish has acknowledged, however, that he is not an expert in immunology. Tr. at 90.

Dr. Gish began his testimony by discussing Petitioner's medical history prior to vaccination—which he deemed not to suggest any developing liver disease or alternative causes. Tr. at 15. For example, she had no physical exam results indicating liver issues, and four normal liver panel tests before receiving the vaccine. *Id*. When a patient has normal liver enzyme tests, "the chance of that person having active liver disease that is hidden in some way is extremely small." *Id*. at 18. He also noted that liver disease patients typically present with symptoms like fatigue, liver pain, jaundice, rashes, and mental confusion. *Id*. at 19. And when reviewing Petitioner's medical history, Dr. Gish looked for common causes of liver disease, such as alcoholism, needle sharing, high-risk sexual behavior, and having medical procedures in developing countries—but no such factors were evident. *Id*. at 19–20. Dr. Gish further pointed out that Petitioner had tested negative for Epstein-Barr virus and Hepatitis B and C, which are significant risk factors. *Id*. at 22.

At most, Petitioner's receipt of anti-malarial medication before traveling to Africa was a risk factor, "but that's typically brief, transient, and doesn't result in autoimmune disease long-term." Tr. at 22. He compared Petitioner's course to that of the patient in a case report whose hepatitis presented acutely after taking an anti-malarial medication. *Id*.; B. Beretta-Piccoli et al*., Atovaquone/Proguanil-Induced Autoimmune-Like Hepatitis,* 1 Hepatology Communications 293 (2017), filed on January 2, 2023, as Ex. A Tab 10 (ECF No. 25-10) ("Beretta-Piccoli"). In contrast to Petitioner, the patient evaluated in Beretta-Piccoli displayed symptoms like jaundice and dark urine early on, which are obvious clinical signs of liver disease. *Id*. at 83. Further, Petitioner had stopped taking all of her medications and supplements after receiving the initial lab results in October 2018 indicating the existence of elevated liver enzymes. *Id*. at 80. Thus, had the two herbal supplements Petitioner had been taking caused her elevated liver enzymes, the levels should have normalized once she stopped taking them—but she continued to have elevated liver enzymes. *Id*. The above, plus Dr. Gish's view that her disease onset had begun within a few weeks of vaccination, permitted him to conclude that she fit the "ideal profile" for an adverse reaction to the vaccine. *Id.* at 22.

To explain how the vaccines Petitioner received could have caused an autoimmune form of hepatitis, Dr. Gish proposed that she had experienced an immune-mediated reaction to the measles component of the MMR vaccine (and although his theories also touched on the Tdap vaccine, he focused more on the MMR vaccine). Tr. at 38. He pointed to filed literature studying both the measles vaccine mechanism in primates, and measles-induced immune suppression in human tissue samples. Tr. at 38–42; R. Nanan et al., *Measles Virus Infection Causes Transient Depletion of Activated T. Cells from Peripheral Circulation*, 12 J. of Clinical Virology 201 (1999), filed on July 11, 2022, as Ex. 31 (ECF No. 19-7) ("Nanan"); T. Munyer et al., *Depressed*

Lymphocyte Function after Measles-Mumps-Rubella Vaccination, 132 J. of Infectious Diseases 75 (1975), filed on July 11, 2022, as Ex. 32 (ECF No. 19-8) ("Munyer").

Dr. Gish theorized that, in clearing the vaccine-induced measles infection from Petitioner's body, non-measles specific immune cells were activated, and stayed chronically activated thereafter, resulting in a chronic autoimmune condition. Tr. at 46–49. In his opinion, Petitioner's immune self-tolerance was broken due to T-cell cross reaction, resulting from the suppression of bystander immune cells by the measles virus, allowing the immune system to attack self antigens (located on the surface or in the mitochondria of liver cells). *Id*. at 58. This autoimmune reaction was later compounded by Petitioner's simultaneous receipt of the Tdap vaccine. *Id*. at 62. Because she had received the Tdap vaccine in the past, he explained, the antigen-specific response generated by this booster vaccine may have amplified the existing response to the measles vaccine. *Id*. Dr. Gish claimed independent medical/scientific literature supported this aspect of his theory, but he did not specify which articles stood for the proposition. *Id.*

Dr. Gish then briefly discussed an item of literature that he proposed was supportive of his theory. S. Subramanian et al., *Postinfectious Autoimmune Hepatitis-Induced Liver Failure: A Consequence of Hepatitis A Virus Infection,* 7 ACG Case Reports J. 1 (2020), filed on July 11, 2022, as Ex. 25 (ECF No. 19-1) ("Subramanian"). But he did not reference Subramanian for its primary findings (which focused on how a hepatitis A infection could secondarily result in autoimmune hepatitis), but instead on a separate item of literature it discussed, "Vento" (which Petitioner never filed in this case). In Vento, researchers followed family groups that developed autoimmune hepatitis after Hepatitis A infections. Tr. at 66–68. The results of the Vento study supported the idea that a genetic disposition made patients susceptible to AIH, and Dr. Gish felt that this in turn suggested that Petitioner was likely genetically susceptible as well. *Id*. at 69. But he admitted that no genetic testing had been performed that would corroborate the contention about Petitioner's susceptibility. *Id*. at 96.

Dr. Gish also reviewed Petitioner's clinical course, deeming it consistent with his causal theory. Tr. at 70. In particular, he opined that Petitioner's AIH symptoms onset began within an acceptable 10-week timeframe for an environmental trigger (in this case the vaccine). *Id*. He pointed to evidence of her fluctuating but elevated liver enzymes between October 2018 and January 2019 as establishing the existence of ongoing AIH, confirmed by the biopsy taken in January 2019. *Id*. at 70–74, 75. Thus, he concluded that "the timing of symptoms, the timing of laboratory tests, the liver biopsy, all fits a classic triggering event and onset of autoimmune disease." *Id*. at 82.

On cross-examination, Dr. Gish acknowledged that he has seen patients who developed AIH after traveling, and after taking herbal supplements as well. Tr. at 91–92. He denied that Petitioner's previous small bowel overgrowth ("SIBO") could have caused her AIH, explaining

that SIBO is linked to a specific type of AIH which Petitioner did not have. *Id*. at 94. He acknowledged that Petitioner's AIH could have been idiopathic, and stated that an environmental trigger can typically only be identified in half of cases. *Id*. at 95.

When asked about the molecular mimicry component of his causal theory, Dr. Gish agreed that he had not identified a specific homology between the MMR and Tdap vaccines and liver proteins. Tr. at 108. He also attempted to explain further the immune suppression mentioned in his earlier testimony and report, and how the MMR vaccine "both suppresses and activates the immune system" at the same time. *Id*. at 112–16. He specified that the innate immune response is suppressed, leading the adaptive immune response to compensate. *Id*. at 113. Concurrently, a variety of antigen-presenting cells are activated, producing "off-target effects." *Id*. Then, in a genetically susceptible individual, "[y]ou end up stimulating an arm of the immune system that isn't getting turned off. These are the T-regs that are suppressed in some ways or can't be activated and the immune system goes down this long pathway." *Id*.

B. Respondent's Experts

1. *Jeffrey Crippin, M.D.* - Dr. Crippin authored one report in this case, and testified at the hearing. Crippin Report, filed on October 31, 2022, as Ex. A (ECF No. 23-1).

Dr. Crippin received his medical degree from the University of Kansas, and completed an internal medicine residency at Kansas University Medical Center, where he served as chief resident. Crippin CV at 1–2, filed on March 4, 2024, as Ex. E (ECF No. 56-1). He then completed a three-year fellowship in Gastroenterology and Hepatology at the Mayo Clinic, Rochester, Minnesota. *Id*. at 2. He currently works at the Barnes-Jewish Hospital in St. Louis, and is a Professor of Medicine at the Washington University School of Medicine. *Id*. at 1. He is board certified in Internal Medicine and Gastroenterology, and has received the Certificate of Added Qualification in transplant hepatology. *Id*. at 6–7. He has extensive experience in patients with autoimmune hepatitis, and has treated 300-400 patients with the disease over the course of his career. Crippin Report at 1.

Dr. Crippin agreed with Petitioner's AIH diagnosis, but denied that the vaccines she received were more likely than not the cause of her illness. Tr. at 123. Rather, he pointed out numerous other potential causal factors in her record, although he was unable to specify a most likely cause. *Id*. at 125–27. These factors included Petitioner's international travel in the months prior to her illness, her use of anti-malarial medication and herbal supplements, and a prior history of kidney stones, an IUD, and her SIBO. *Id.* at 125–27, 128–29. Further, she had tested positive for Epstein-Barr virus antibodies in December 2018. *Id*. at 127; Ex. 3 at 207. He admitted, however, that it was impossible to determine *when* she had Epstein-Barr from that test—"It could have been earlier that year, it could have been five years ago." *Id.* Although she experienced fatigue

(a symptom of the virus) upon returning from travel, she was not tested for the virus at the time. *Id*. at 128. He also noted that a large number of AIH cases are idiopathic, meaning that no specific trigger can be identified. *Id*. at 130.

Dr. Crippin then discussed one of the case reports Petitioner filed, pointing out differences from Petitioner's clinical course. *Id*. at 131; W. Saliba & M. Elias, *Acute Hepatitis Following MMR Vaccination*, 16 European J. of Internal Medicine 379 (2005), filed on July 11, 2022, as Ex. 21 (ECF No. 18-6) ("Saliba"). Saliba featured a patient who experienced *acute* hepatitis rather than AIH, and no liver biopsy was performed to help determine the cause. *Id*. at 131; The patient had also recently given birth, putting her at greater risk of viruses due to pregnancy-related immune suppression. Tr. at 131–32. Further, the Saliba patient developed symptoms of her liver illness within two weeks of vaccination, whereas Petitioner first exhibited potential symptoms no sooner than six to eight weeks after vaccination. *Id.* at 132.

Dr. Crippin also noted that he had not been able to locate any controlled studies showing a link between AIH and either the MMR or Tdap vaccines. Tr. at 130. And he similarly was unaware of studies showing the combined administration of both vaccines at once was a risk factor for AIH. *Id.* at 133. On cross, he reiterated his prior testimony that he could not determine the time when Petitioner was infected with Epstein-Barr virus, and that there were no other infections noted in her records. *Id*. at 135. Ultimately, he declined to identify which of the various factors he deemed the most likely cause, and stated again that this could be an idiopathic case. *Id.* at 137–38, 140–41.

2. *Andrew MacGinnitie, M.D., Ph.D.* - Dr. MacGinnitie wrote one report in this case, and testified at the hearing. MacGinnitie Report, filed October 31, 2022, as Ex. C (ECF No. 23-3) ("MacGinnitie Rep.").

Dr. MacGinnitie is the Chief of the Division of Allergy, Asthma, and Immunology at Children's Hospital of Wisconsin, and a Professor of Pediatrics at Medical College of Wisconsin. Tr. at 142–43. He graduated from the University of Chicago Pritzker School of Medicine with both an M.D. and a Ph.D. from the Department of Pathology. MacGinnitie CV, filed on October 31, 2022, as Ex. D (ECF No. 23-4) He then completed a residency in Pediatrics in the Boston Combined Residency Program, training at Boston Children's Hospital and Boston Medical Center, followed by an Allergy/Immunology fellowship at Boston Children's Hospital. *Id*. He is board certified in both Allergy/Immunology and Pediatrics. *Id.* at 11. He maintains an active clinical practice seeing more than 1600 patients annually and has extensive experience in caring for children and adults with a variety of immunologic diseases, including reactions to vaccines. MacGinnitie Report at 2. Dr. MacGinnitie also performs research, and has published articles in a number of areas related to Allergy/Immunology including food allergy, vaccine reactions, and primary immunodeficiency. *Id.*

Dr. MacGinnitie opined that the vaccines Petitioner received had no relationship to her AIH. Tr. at 148. First, he criticized Dr. Gish's reliance on case reports in the absence of epidemiological studies connecting AIH and the Tdap and MMR vaccines. Tr. at 150. In his view, case reports cannot reliably connect a vaccine to an illness because they do not provide an accurate comparison with the baseline rate of an illness in the general population. *Id.* Further, none of the case studies filed involved the effects of simultaneous administration of the Tdap and MMR vaccine in causing AIH. *Id.* at 151; *see,* e.g., M. van Gemeren et al., *Vaccine-Related Autoimmune Hepatitis: The Same Disease as Idiopathic Autoimmune Hepatitis? Two Clinical Reports and Review*, 52 Scandinavian J. of Gastroenterology 18 (2017) (combination of Tdap and hepatitis A vaccine), filed on July 11, 2022, as Ex. 26 (ECF No. 19-2); *see also* P. Perumalswami et al., *Vaccination as a Triggering Event for Autoimmune Hepatitis*, 29 Seminars in Liver Disease 331 (2009) (hepatitis A and yellow fever vaccines), filed on March 6, 2024, as Ex. 27 (ECF No. 61). At best, Saliba involved the MMR vaccine, but the injury therein was acute hepatitis rather than AIH (a chronic condition). *Id*. at 152; Saliba. In another, the patient received six vaccines at the same time, and although the MMR was one of them, it was impossible, in Dr. MacGinnitie's opinion, to isolate the effects of only one or two. *Id.* at 152–53; G. Veerappan et al., *Vaccination-Induced Autoimmune Hepatitis,* 50 Digestive Diseases and Sciences 212 (2005), filed on March 5, 2024, as Ex. 24 (ECF No. 58-1).

Dr. MacGinnitie next criticized Petitioner's molecular mimicry theory. Tr. at 156. After explaining the concept briefly, he noted that Dr. Gish had not identified any specific homology (meaning molecular similarity) between the vaccines and the liver cell antigens where an autoimmune cross-reaction would begin or occur—a crucial starting point if molecular mimicry was a reasonable explanation for Petitioner's injury. *Id*. at 158. Even if he had, however, it would not be sufficient to prove the theory in Dr. MacGinnitie's view, as there is a "massive overlap between microbial and human proteins" in nature, but which does not commonly result in autoimmunity. *Id*. at 158. He also criticized Petitioner's reliance on bystander activation as a disease mechanism, noting that articles filed in the case regarding AIH did not consider this to be a pathologic explanation. *Id.* at 160; C. Mack et al., *Diagnosis and Management of Autoimmune Hepatitis in Adults and Children: 2019 Practice Guidance and Guidelines from the American Association for the Study of Liver Diseases*, 72 Hepatology 671 (2020), filed on January 26, 2023, as Ex. A, Tab 1 (ECF No. 25-1). Beyond this, Petitioner had not displayed clinical signs of significant inflammation, which would have occurred shortly after vaccination had such an autoimmune response occurred. *Id*. at 159.

Dr. MacGinnitie also addressed Petitioner's argument that her immune system was likely suppressed by the measles vaccine, allowing an autoimmune response to occur. He noted the absence of strong evidence showing that the measles *vaccine* (as opposed to the wild virus) suppresses the immune system to any pathologic degree. Tr. at 162; MacGinnitie Rep. at 8–9. And

he deemed articles filed to support this contention as lacking in clinical value or were outdated. *Id*. at 162–64; Nanan (published in 1999); Munyer. Up-to-date clinical manuals relied upon by treaters, however, acknowledge the immune-suppressive nature of the wild measles virus, but not the vaccine (the receipt of which functions to *prevent* this immune suppression in the first place). Tr. at 165–66; AMERICAN ACADEMY OF PEDIATRICS, RED BOOK (2021): REPORT OF THE COMMITTEE ON INFECTIOUS DISEASES 503 (32d ed. 2021), filed on January 26, 2023, as Ex. C, Tab 4 (ECF No. 26-4); *see also* M. Mina, *Measles, Immune Suppression, and Vaccination: Direct and Indirect Nonspecific Vaccine Benefits,* 74 J. Infection S10, S15 (2017), filed as Ex. C., Tab 3 (ECF No. 26-3) (noting the benefit of measles vaccine in blunting the immunosuppressive character of a wild measles virus infection). He also noted that the theory did not fit how AIH occurs. Since AIH is autoimmune in character, it reflects an aberrant *overstimulated/* overactive immune process—not one that has been suppressed (and thus a measles infection-like reaction might actually *reduce* the possibility of an autoimmune process developing). *Id*. at 162.

Dr. MacGinnitie challenged Dr. Gish's argument that whole cell pertussis[3] could itself stimulate a class of T-helper cells (which encourage the production of certain proinflammatory cytokines)—and thus, because Petitioner had likely received the whole cell pertussis vaccine as a child, the Tdap booster she had received in 2018 might have increased the possibility of a comparable memory response. Tr. at 169. He acknowledged the importance of the relevant T-helper cells in fighting bacterial and fungal infections, but deemed the re-stimulation of them unlikely to cause autoimmune disease. *Id.* at 170. Thus, although Petitioner had offered a study showing that patients vaccinated with whole cell pertussis produced more inflammatory cytokines than those vaccinated with acellular pertussis, the study did not establish that the levels of produced cytokines were anywhere near levels sufficient to propagate an autoimmune inflammatory environment. *Id*. at 171–72; R. Antunes et al., *Th1/Th17 Polarization Persists Following Whole-Cell Pertussis Vaccination Despite Repeated Acellular Boosters*, 128 J. Clinical Investigation 3853 (2018), filed on July 11, 2022, as Ex. 34 (20-1). And since Petitioner had not been tested for these cytokines, it was pure speculation to propose she had possessed them in pathologic levels after vaccination. *Id*. at 173.

Dr. MacGinnitie concluded with a brief consideration of the onset interval of one to five months Dr. Gish proposed for vaccine-induced AIH. Tr. at 174. Although he opined that case reports should carry little evidentiary weight, he noted that the case reports Dr. Gish cited showed documented hepatitis (not simply the first symptoms) had begun within a far shorter timeframe: within ten to thirty days of vaccination. *Id*. at 174; see, for example, T. Sasaki et al., *Autoimmune Hepatitis Following Influenza Virus Vaccination: Two Case Reports*, 97 Medicine 1 (2018), filed on July 11, 2022, as Ex. 28 (ECF No. 19-4) (one week onset and one month onset). Other items of

[3] The now largely-discontinued DPT vaccine included whole cell pertussis, but the version administered today (Tdap) employs an acellular form of pertussis thought to be less likely to cause certain side effects. *See Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367 n1 (Fed. Cir. 2009) for discussion of case law on the safety concerns prompting the switch to an acellular formulation.

literature Petitioner referenced for a shorter onset timeframe involved distinguishable diseases or other vaccines. Tr. at 175–76; L. Schonberger et al., *Guillain-Barré Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976-1977*, 110 Am. J. of Epidemiology 105, filed on March 21, 2023, as Ex. 39 (ECF No. 28-2) (flu vaccine and Guillain-Barré syndrome).

III. Procedural History

As noted above, the case was initiated in 2021. Respondent filed his Rule 4(c) Report disputing Petitioner's right to compensation on August 19, 2022. Expert reports were filed through the end of 2022, the trial was held in March 2024, and the matter is now ripe for resolution.

IV. Applicable Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[4] There is no Table injury for AIH, so Petitioner can only assert a causation-in-fact claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions;

[4] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health and Hum. Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each *Althen* prong requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245 ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)).

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Kalajdzic v. Sec'y of Health & Hum. Servs.*, No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) (arguments "for a less than preponderance standard" deemed "plainly inconsistent with our precedent" (*citing Moberly*, 592 F.3d at 1322)); *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also Howard v. Sec'y of Health & Hum. Servs*., 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *aff'd*, 2024 WL 2873301 (Fed. Cir. June 7, 2024) (unpublished). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell*

v. United States, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd*

mem., 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also*

Murphy v. Sec'y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the

factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations");

see also Porter v. Sec'y of Health & Hum. Servs., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

ANALYSIS

The failure to establish even one of the three *Althen* prongs in the context of a causation-in-fact claim is sufficient basis for a claim's dismissal. *Dobrydnev v. Sec'y of Health & Hum. Servs*., 566 Fed. Appx. 976, 980 (Fed. Cir. 2014). Petitioner could not preponderantly establish prongs one and two.[5]

First, Petitioner has not preponderantly established that it is likely that the MMR and Tdap vaccines—alone or in combination—*can cause* AIH. Dr. Gish's opinion (which goes a bit beyond his expertise in hepatologic matters and into immunology) has some reliable points in its favor, but ultimately fails to persuasively "connect the dots" into a causal explanation. His points about the immune-suppressive character of the MMR vaccine, for example, relied on a false equivalence between the impact of the measles wild virus and vaccine, attempting to treat the impact of the two as the same.[6] In fact, as Dr. MacGinnitie noted, the measles vaccine's impact is to make immune suppression less likely—and there is a contradictory quality to arguing that immune suppression

[5] I thus need not also evaluate the sufficiency of Petitioner's third prong showing under the circumstances.

[6] *See,* e.g., Tr. at 37 (Dr. Gish responding affirmatively to the question, "[w]ould it be expected that Mrs. Exum suffered a mild vaccine strain measles infection from the administration of her vaccine?"). But this kind of argument has been rejected in the Program before. *See,* e.g., *Snyder v. Sec'y of Health & Hum. Servs.*, No. 01-162V, 2009 WL 332044, at *104 (Fed. Cl. Spec. Mstr. Feb. 12, 2009) ("petitioners have failed to demonstrate that the MMR vaccine causes immunosuppression. There is no evidence that children receiving the vaccine have higher rates of infection in the months after vaccination than children who do not receive the vaccine"), *mot. for review den'd,* 88 Fed. Cl. 706 (2009).

would cause a disease reaction that occurs due to an uncontrolled immune response. He similarly made assumptions about the impact of the Tdap vaccine (and its promotion of inflammation through stimulation of T-helper cells) that rely more on supposition than independent evidence—and he could not imbue these contentions with reliability by drawing on immunologic expertise he lacks. And the idea that both vaccines administered at the same time raise the risk of an aberrant response is a barely-plausible contention that lacked corroboration from materials filed in this case.

More generally, it was not shown that the vaccines at issue could likely promote an autoimmune response resulting in AIH—and consideration of the typical "building blocks" relied upon by petitioners in comparable Program cases illuminates why. Autoimmune diseases involve mistaken self-attacks propagated by antibodies generated in response to a foreign antigen that (due to molecular and/or structural similarities with a self-antigen protein) then cross-react with the self tissue, often in a chronic/persistent manner. *See,* e.g., *Bielak v. Sec'y of Health & Hum. Servs.*, No. 18-761V, 2023 WL 35509, at *33 (Fed. Cl. Spec. Mstr. Jan. 3, 2023) ("[m]olecular mimicry is predominantly driven by B cell activity, occurring when antibodies are produced in response to antigenic components of the vaccine—but which (due to mimicry between the presenting vaccine antigens and self-tissues) cause harmful cross-reactions, by mistakenly attacking the self antigens").

Thus, litigants commonly attempt to show at a minimum (a) what homology might exist between a vaccine's antigens and a self structure relevant to the situs of harm (here the liver), and (b) what evidence exists that the vaccine would cause the production of the likely pathogenic antibodies. See *K.A. v. Sec'y of Health & Hum. Servs.*, No. 16-989V, 2022 WL 20213037, at *9 (Fed. Cl. Spec. Mstr. Apr. 18, 2022), *mot. for review den'd*, 164 Fed. Cl. 98 (2022), *aff'd*, 2024 WL 2012526 (Fed. Cir. May 7, 2024) ("[b]ecause homology is common in nature (given the total limited number of amino acids that constitute proteins), it is important to focus on homology specific to the "disease-related" situs for the cross-reactive attack"). Here, however, Dr. Gish has not made this showing—which, as Dr. MacGinnitie noted, is by itself not necessarily sufficient evidence to conclude an autoimmune process linked to vaccination has been established. And case reports (only a few of which, like Saliba, even involved a relevant vaccine) are known to be weak evidence of causation. *Campbell v. Sec'y of Health & Hum. Servs.*, 97 Fed. Cl. 650, 668 (2011) ("'[c]ase reports do not purport to establish causation definitively, and this deficiency does indeed reduce their evidentiary value,' even if they should receive some weight").

Second, the record does not support the conclusion that Petitioner's vaccinations caused her AIH. Nothing in the medical record (beyond the symptoms Petitioner began to experience post-vaccination) tends to support the conclusion that the vaccines caused her AIH—and to determine otherwise would be to elevate the temporal relationship between vaccination and injury into evidence of causation. *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992) ("[a] proximate temporal association alone does not suffice to show a causal link

between the vaccination and the injury").[7] More important are the circumstances in which Petitioner received these vaccines. While Dr. Gish did observe the absence of many risk factors for AIH relevant to Petitioner, he did not persuasively limit or exclude all of them. Petitioner's recent post-vaccination foreign travel, plus her acknowledged receipt of anti-malarial medications and supplements, her IUD, and her Epstein-Barr infection were all reasonably-likely causal factors.[8] In this context, there are too many other possible explanations to find the vaccines were a substantial factor as well (especially given the thin showing overall on the "can cause" prong)—and collectively they further undermine Petitioner's showing.

I so conclude even though I do not purport to identify what *was* the most likely cause of Petitioner's AIH, based on the record before me. But even though claimants are never obligated to rule out alternative causes as part of their initial burden, special masters may of course consider evidence in the record undermining vaccine causation when evaluating whether the second *Althen* prong has been established. *Stone v. Sec'y of Health & Hum. Servs.*, 676 F.3d 1373, 1380 (Fed. Cir. 2012) ("[t]he special master is entitled to consider the record as a whole...and no evidence should be embargoed from the special master's consideration simply because it is also relevant to another inquiry under the statute."). I can thus legitimately determine vaccination was not likely causal of Petitioner's AIH, even if I cannot conclude what *was* most likely causal.

CONCLUSION

A Program entitlement award is only appropriate for claims supported by preponderant evidence. Here, Petitioner has not made such a showing. Petitioner is therefore not entitled to compensation.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[9]

[7] For this same reason, I do not give weight to the *pre-vaccination* absence of evidence of liver disease or hepatitis as proof of the vaccine's role in causing what manifested after. The fact a claimant was not sick before the vaccination, but sick after, is simply another form of *post hoc ergo propter hoc* reasoning that the Program rejects.

[8] At most, Dr. Gish distinguished the malarial medication as likely causal, with his arguments about the more abrupt form of AIH that seemed to be evident in Beretta-Piccoli. But his contentions about her mere cessation of these medications as undermining a causal role were unpersuasive—especially since Petitioner herein maintains a *one-time* receipt of two vaccines resulted in a chronic/persistent disease process.

[9] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.

IT IS SO ORDERED.

s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master